relationship between alcohol impairment and accidents. In preferred embodiments, the test is used following alcohol consumption as a method for aiding the determination of fitness to drive. If the test indicates blood alcohol concentration (BAC) levels associated with risk of driving, the consumer chooses not to drive, reducing the risk of accidents. In some embodiments, a group of alcohol consumers are each tested to determine the most suitable driver or drivers within the group. In other embodiments, an alcohol consumer, upon receiving a result indicating impairment, waits for a time period and conducts subsequent testing until the results suggest fitness to operate a motor vehicle. In some embodiments, the assay tests are provided with time-consuming materials to help occupy the consumers' time between testing events. In other embodiments, information (e.g., taxi information) is provided to assist the consumer in selecting a safe course of action if the test indicates a lack of fitness.

In some embodiments of the present invention, alcohol providers such as bars, restaurants, and alcohol manufacturers and distributors provide alcohol concentration tests to consumers. For example, in some embodiments, a restaurant may implement a wait-and-retest program (*e.g.*, providing multiple tests and educational information and/or incentives such as free non-alcoholic beverages until a suitable test result is obtained).

In preferred embodiments, the alcohol concentration assays tests are stable in the for at least one month, preferably for at least six months, more preferably for at least one year, and most preferably for at least two years. For example, in some embodiments, the assay test is temperature stable and possesses a long shelf life (*e.g.*, maintains function for over a year at room temperature and for over three months at 104 °F).

A wide variety of reaction means are compatible with the present invention. In preferred embodiments, acceptable reaction means are those that can be incorporated into the assay tests of the present invention and that can generate and maintain a detectable signal in the presence of alcohol (*e.g.*, methanol, ethanol, etc.). In some embodiments, the reaction means is selected and tailored to achieve desired reaction speed, accuracy, reliability, cost, and durability. For example, a variety of chemical

reactions that provide colorimetric detection of ethanol in a sample are described in U.S. Patents 5,032,506, 4,629,697, 4,642,286, 5,290,683, 5,589,349, 5,429,932, 5,429,931, 5,416,004, 4,786,596, 4,810,633, 4,734,360, 5,525,481, 5,141,854, 5,403,749, incorporated herein by reference in their entireties.

In preferred embodiments, the chemicals used at the reaction site are non-toxic, non-irritant and/or are not carcinogenic. This presents a problem because many chromogens cause toxic reactions, irritation or are carcinogenic if used orally. In contrast, the present invention provides chemistries that are non-toxic, non-irritant and/or non-carcinogenic. Indeed, any non-toxic, non-irritant and/or non-carcinogenic chromogen finds use with the present invention. A chromogen with unknown toxicity can be tested for toxicity by exposing several doses of the material to a test subject (*e.g.*, an animal or human) and detecting undesired toxic responses. If no undesired toxic responses are observed when the chromogen is used at a functional (*e.g.*, colorimetric) concentration, when exposed to the subject in a manner consistent with the methods of the present invention (*e.g.*, placed in the mouth of a subject on a colorimetric test strip), then the candidate compound may be designated non-toxic and incorporated into the test assays of the present invention. The protocol in Example 1 may be followed to determine whether or not a candidate material for use in the reaction site of the test assay is toxic/non-toxic or an irritant/non-irritant. To avoid carcinogenicity, components of the reaction means are selected such that they are known not to have carcinogenicity (See e.g., CRC Handbook of Identified Carcinogens and Noncarcinogens). For compounds where the carcinogenicity is unknown, testing can be conducted to determine whether the candidate compound is, or is not, a carcinogen using any technique known in the art.

In some embodiments, the present invention provides potassium iodide (KI) as a chromogen. Assay tests containing potassium iodide were tested as non-toxic and non-irritant using the protocol in Example 1. Potassium iodide is an approved food additive whose use at 0.01% in iodized salt is well recognized. The amount of potassium iodide used in an assay test (e.g., 133 micrograms) is equivalent to the amount contained in 1-2 grams of iodized salt, and presents no safety concerns.

Potassium iodide was found to provide a stable, detectable, colorimetric chromogen for use in the assay tests of the present invention. Potassium iodide also provides a chromogen suitable for use in on/off type assay readouts. Embodiments employing non-toxic chromogens are described in detail below.

In preferred embodiments, the reaction site of the present invention provides an on/off readout if the alcohol concentration level of the sample is above a certain threshold concentration. For example, an assay test designed to detect a sample concentration equivalent to a blood alcohol concentration of 0.04% would not change color at concentration significantly under 0.04% (off), but would change color at concentrations at or above 0.04% (on). The on/off format can be accomplished, for example, by the addition of competitive inhibitors or scavengers that prevent the colorimetric reaction unless the threshold concentration is reached, whereupon the competitor or scavenger is swamped out and the substrate is available to initiate the colorimetric reaction. Embodiments employing on/off reactions are described in detail in the example section below. In yet other embodiments, the detection readout is a gradient readout, wherein the color change gradually increases in intensity with an increase in alcohol concentration. In some embodiments, both on/off and gradient detections readouts are combined in a single assay. In some embodiments of the present invention, multiple collection sites and reaction sites are used. The plurality of collections sites find use, for example, in detecting different threshold concentrations of alcohol (*e.g.*, a first collection site that detects 0.4% and a second collection site that detects 0.8%), different detectable readouts (*e.g.*, different colors or a first collection site that shows a color and a second collection site that produces a symbol, shape, or word), different read-out formats (*e.g.*, a first collection site that uses an on/off readout and a second collection site that uses a gradient readout), different detection purposes (*e.g.*, detection versus indicator or detection of different analytes) and the like.

In some preferred embodiments, stabilizers are used to make the assay test durable. For example, in some embodiments of the present invention, the assay tests of the present invention remain functional for over a year when maintained at room